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No. 83-1925

In the Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, ET AL., APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and their implementing rules and regulations pertaining to the collection of blood plasma from paid donors are preempted by regulations adopted by the Food and Drug Administration governing blood and blood products, including blood plasma and plasmapheresis.

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INTEREST OF THE UNITED STATES

The question presented by this case is whether the regulations promulgated by the Food and Drug Administration (FDA) governing blood, blood components, blood products, and plasmapheresis preempt Hillsborough County, Fla., Ordinances 80-11 and 80-12 (Nov. 26, 1980) and their implementing Rules and Regulations. The United States, through the FDA, has the primary responsibility for ensuring the safety, purity, and potency of blood, blood components, and blood products distributed in interstate and foreign commerce and thus has a substantial interest in ensuring that the federal regulations governing these matters are construed in a manner that advances, rather than impedes, their objectives.

STATEMENT

A. The Federal Regulatory Scheme

The Public Health Service Act, 42 U.S.C. 262 *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, authorize the Department of

Health and Human Services (HHS) to regulate blood and blood products as biological products (42 U.S.C. 262)[1] and as drugs (21 U.S.C. 321(g)(1)).[2] Under Section 351(a) of the Public Health Service Act, 42 U.S.C. 262(a), manufacturers and vendors of biological products, including blood products and their derivatives, must be licensed by the Secretary of

[1] Section 351 of the Public Health Service Act, as amended by Section 291 of the Heart Disease, Cancer, Stroke and Kidney Disease Amendments of 1970, Pub. L. No. 91-515, 84 Stat. 1308, 42 U.S.C. 262, forbids the manufacture or sale in interstate or foreign commerce of any "blood, blood component or derivative" without a license from the Secretary of HHS. See 39 Fed. Reg. 18614 (1974); 38 Fed. Reg. 2965 (1973). Blood plasma is subject to the Act. *United States* v. *Steinschreiber*, 218 F. Supp. 426, 427-428 (1962), supplemented, 219 F. Supp. 373 (S.D.N.Y. 1963), aff'd, 326 F.2d 759 (2d Cir.) (per curiam), cert. denied, 376 U.S. 962 (1964); *United States* v. *Calise*, 217 F. Supp. 705, 708-709 (S.D.N.Y. 1962); see page 15 note 14, *infra*.

[2] Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(g)(1), defines a "drug" to include "(A) articles recognized in the official United States Pharmacopeia * * * and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." Blood was first listed in the United States Pharmacopeia in 1955 (38 Fed. Reg. 2965 (1973)), and it has been included in every subsequent edition. Blood, blood components, and blood products also serve the therapeutic purposes identified in the statute and thus qualify as "drugs" for that reason as well. *Ibid.*; see also 39 Fed. Reg. 18614 (1974); *Blank* v. *United States*, 400 F.2d 302, 305-306 (5th Cir. 1968); *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 392 F.2d 21, 23 (6th Cir. 1968), rev'd on other grounds, 394 U.S. 784 (1969); *United States* v. *Calise*, 217 F. Supp. 709; cf. *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 793 (1969) ("[v]iewing the structure, the legislative history, and the remedial nature of the Act, we think it plain that Congress intended to define 'drug' far more broadly than does the medical profession").

HHS. Licenses are issued only upon a showing that the manufacturer's or vendor's establishment and products meet certain safety, purity, and potency standards established by the Secretary. 42 U.S.C. 262(d). HHS is authorized to inspect such establishments for compliance as it sees fit. 42 U.S.C. 262(c).

Pursuant to Section 351, 42 U.S.C. 262, the Food and Drug Administration's Office of Biologics Research and Review, as the designee of the Secretary,[3] regulates various types of blood products and blood banking activities, including blood plasmapheresis procedures. 21 C.F.R. Pts. 600, 601, 606, 607, 610, 640.[4] Under 21 C.F.R. Part 640, Subpart G, the FDA has established standards for plasma collected by plasmapheresis. 21 C.F.R. 640.60-640.76. These standards were adopted, and are revised from time to time, to ensure the safety, purity, and potency of the final products derived from plasma[5] and to protect plasmapheresis donors from possible abuses ranging from the collection of excessive quantities of plasma to the use of medical or collection procedures that could endanger a donor's health. See 39 Fed. Reg. 26161 (1974). The regulations require, inter alia, that a plasma center obtain the informed consent of donors before plasmapheresis is performed and that a

[3] Pursuant to Section 361 of the Public Health Service Act, 42 U.S.C. 264, and under the authority delegated to him by the Secretary (21 C.F.R. 5.10), the Commissioner of Food and Drugs is authorized to promulgate regulations to implement the Act.

[4] Plasmapheresis is defined as "the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor." 21 C.F.R. 606.3(e); see also J.S. App. A3, A14.

[5] Plasma derivatives include such products as hepatitis vaccine, albumin, and antihemophilic factor. See, *e.g.*, 21 C.F.R. 610.41, 640.50, 640.80.

licensed physician both examine a potential donor before he or she is accepted and be present on the premises while the procedure is being performed. 21 C.F.R. 640.61-640.63.[6] The regulations establish minimum standards for donor eligibility, for conducting plasmapheresis, and for processing, storing, and labeling plasma units obtained during the procedure. 21 C.F.R. 640.63, 640.65, 640.68, 640.70. Recordkeeping requirements are also imposed. 21 C.F.R. 640.72. The Director of the Office of Biologics Research and Review has the power to approve variances from any of the requirements of Subpart G. 21 C.F.R. 640.75.

B. The Hillsborough County Ordinances And Regulations

In November 1980, Hillsborough County, Florida, adopted County Ordinances 80-11 and 80-12 (J.S. App. A29-A39), which govern the licensing and operation of commercial blood plasma donor centers. Ordinance 80-11 imposes a license fee on plasmapheresis centers, while Ordinance 80-12 "provide[s] a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County" (J.S. App. A32-A33). In addition to incorporating by reference the FDA's blood plasma regulations (*id.* at A38-A39), Ordinance 80-12 imposes certain additional donor testing and recordkeeping requirements not contained in 21 C.F.R. Part 640, Subpart G. Among other things, Ordinance 80-12 requires that plasma donors be issued county identification cards that restrict them to donating at one

[6] The FDA has construed those regulations to mean that a physician may be constructively on the premises if he is able to arrive within 15 minutes after being called. See FDA, *Instruction Booklet for Plasmapheresis Inspection Checklist and Report, Form FDA 2722*, at 1-2 (Sept. 1981).

particular center; it also requires that each donor be tested for hepatitis prior to registration[7] and be given a breath analysis for alcohol content before each plasma donation. Ordinance 80-12, §§ 4, 6(A) and (D), 7 (J.S. App. A33-A34, A35-A36). The County has issued Rules and Regulations to implement the ordinances (*id.* at A40-A42). Together, the ordinances and regulations impose a variety of requirements upon paid blood plasma donors and commercial blood plasma centers that are not found in the FDA's blood plasma regulations.

C. The Proceedings Below

1. Appellee Automated Medical Laboratories, Inc. (AML) is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, including Tampa Plasma Corporation (TPC) in Hillsborough County (J.S. App. A14). TPC collects blood plasma from paid donors by plasmapheresis (*ibid.*).[8] Following Hillsborough's adoption of Ordinances 80-11 and 80-12, appellee filed this action against the County and its health department in the United States District Court for the Middle District of Florida, challenging, on several grounds, the constitutionality of the Ordinances and the Rules and Regulations adopted to implement them. In November 1982, following a bench trial, the court issued an opinion sustaining all but one aspect of the ordinances and regulations (J.S. App. A13-A19).

The district court found no evidence of "express congressional intent to occupy the entire field of as-

[7] Under federal regulations, testing for hepatitis-positive plasma is performed after plasmapheresis is completed. See 21 C.F.R. 640.67, 640.75.

[8] The steps that TPC follows are described in the opinions below. See J.S. App. A3-A4, A15; see also 1 Tr. 27-34.

suring high standards of practice in plasmapheresis" and concluded that the ordinances supplement the federal regulations, rather than conflict with them (J.S. App. A17). The court also held that the ordinances did not violate the Equal Protection Clause of the Fourteenth Amendment and that most of the challenged provisions did not impermissibly burden interstate commerce (J.S. App. A17-A18). With respect to the breathalyzer requirement, however, the court held that the County had not demonstrated that such a provision would serve the public interest to any greater degree than the federal regulations (*id.* at A19). Accordingly, the court held that the provisions relating to that requirement (Section 7 of Ordinance 80-12 and Section 4 of the implementing Rules and Regulations (J.S. App. A35-A36, A41)) impermissibly burdened interstate commerce and were thus invalid (*id.* at A19).

2. The court of appeals affirmed in part and reversed in part. The court held that the FDA's blood plasma regulations preempted all provisions of the County's ordinances and regulations (J.S. App. A1-A12). The court of appeals first noted that the federal regulatory scheme was "comprehensive" and stated that its "pervasiveness * * * makes it reasonable to infer that Congress [*sic*: the FDA] left no room for local ordinances to supplement it" (*id.* at A8-A9). The court also concluded, based on statements by the FDA regarding the establishment of a National Blood Policy, that the field of plasmapheresis was one in which the federal interest was dominant over any state or local interest (*id.* at A9-A10). Finally, the court ruled that the additional requirements imposed on plasma centers by the County's ordinances were "burdensome and expensive" and would interfere with "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors" (*id.* at A11).[9]

SUMMARY OF ARGUMENT

Pursuant to its statutory authority, the FDA has promulgated comprehensive regulations governing the collection of blood and blood components and the manufacture of blood products. Among those regulations are rules governing plasmapheresis, the process by which whole blood is removed from a donor, blood plasma is separated from the donor's whole blood, and the remaining blood components are returned to the donor. The purpose of the FDA regulations is to establish the nationwide standards necessary to provide an adequate supply of safe, pure, and potent blood, blood components, and blood products as well as to protect the health of blood donors. Hillsborough County has also enacted a regulatory scheme governing these matters, which, in addition to incorporating the federal regulations, imposes additional licensing, certification, recordkeeping, reporting, and inspection requirements upon vendors and donors within the County.

In this case, the court of appeals held that the Hillsborough County regulatory scheme was implicitly but completely preempted by the federal regulations. The reasons given by the court for its ruling are unsound, however. The federal regulations do not expressly foreclose any supplementary state or local regulation of this subject, and, with one potential ex-

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[9] Because of the court of appeals' preemption ruling, the court declined to decide whether the Hillsborough County ordinances and regulations, in whole or in part, violated the Commerce Clause or the Equal Protection Clause (J.S. App. A12). Were the Court to reverse the judgment of the court of appeals, these issues would be open on remand. The United States takes no position on these questions.

ception, the Hillsborough ordinances and regulations do not conflict with the FDA's regulations or interfere with federal policies in this area. Thus, while the FDA does not endorse the Hillsborough County regulatory scheme as a matter of policy and may someday decide to preempt such local regulations if their widespread adoption threatens to hamper the agency's ability to assure that an adequate supply of blood plasma is available to meet the nation's medical and scientific needs, it is the position of the FDA that this particular local regulatory scheme is not wholly superseded by federal law. Accordingly, aside from one provision that may conflict with the FDA's regulations and would therefore be preempted, the judgment of the court of appeals should be reversed.

1. Hillsborough Ordinances 80-11 and 80-12 and their implementing Rules and Regulations are not explicitly preempted by any federal statute or regulation. Two federal statutes, the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, empower the FDA to regulate blood, blood components, and blood products, but neither Act expressly forecloses supplementary state or local regulation of plasmapheresis or can reasonably be construed to establish a federal monopoly over this field. Nor do the federal regulations governing this subject expressly preempt supplementary regulation of the type enacted by Hillsborough County or imply that the federal rules shall be the sole standards governing this field. The court of appeals was thus correct in ruling that neither Congress nor the FDA expressly intended to displace state and local authority in this area.

In fact, the FDA expressly disclaimed any intent to oust the states and local governments from the plasmapheresis field at the time the FDA originally adopted the plasmapheresis regulations at 21 C.F.R. Part 640. That contemporaneous statement of the

agency's intent regarding the proper scope of its own regulations is dispositive of the issue presented by this case.

2. The court of appeals thus erred in ruling that the FDA's regulations implicitly but completely displace the Hillsborough regulatory scheme. None of the reasons given by the court of appeals for finding that the Hillsborough ordinances and rules were implicity preempted is sufficient to justify complete preemption. The comprehensive scope of the FDA's regulations is the product of the FDA's dual goals of protecting product and donor safety as well as the complex and technical nature of the subject matter, rather than the agency's intent to preempt state law. Moreover, while the agency has the primary responsibility for regulating this subject on a nationwide basis and has adopted regulations to ensure that the nation's medical and scientific needs are fully met, the field of blood plasma regulation is not one in which national policies will inevitably be disrupted if the states and local governments also share in the effort to protect the public health. Finally, the Hillsborough ordinances and regulations, with one exception, do not at this time impose requirements that conflict with those established by federal law or impede the federal government from accomplishing stated federal goals. Complete preemption is thus unjustified.

3. The Hillsborough ordinances and regulations may be preempted in one respect. Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations forbid plasma donors from undergoing plasmapheresis until an examining physician has issued a "Certificate of Good Health" as required by the FDA's regulations. However, the FDA authorizes specific plasmapheresis facilities to collect blood from donors who could not receive such a certificate, in order to produce certain vaccines and

diagnostic products. 21 C.F.R. 610.41, 640.75. To that extent, the Hillsborough regulatory scheme may conflict with the authority granted specific plasmapheresis centers by the FDA's regulations.

Appellee appears to lack standing to raise this issue, however, because the complaint does not allege that either appellee or its subsidiary operating in Hillsborough County has received an exemption from the FDA to collect blood from donors with a history of hepatitis. In addition, the County's regulations may be intended to incorporate the FDA's regulations that allow plasmapheresis centers to obtain an exemption. If so, there would be no conflict between the federal regulations and the County's regulatory scheme, and preemption would be unjustified.

ARGUMENT

I. THE HILLSBOROUGH COUNTY ORDINANCES AND REGULATIONS ARE NOT WHOLLY PREEMPTED BY FEDERAL LAW

A. Introduction

1. It is a familiar and well-established principle that the Supremacy Clause of Article VI, Clause 2, invalidates state laws that "interfere with, or are contrary to" federal law. *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824). Under the Supremacy Clause, federal law may supersede state law in several different ways. First, when acting within constitutional limits, Congress is empowered to preempt state law by so stating in express terms. *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977). In the absence of express preemptive language, Congress's intent completely to preempt state law in a particular area may be inferred because the scheme of federal regulation is so comprehensive as to make reasonable the inference that Congress "left no room" for supplementary state regulation. *Rice* v. *Sante Fe Elevator*

Corp., 331 U.S. 218, 230 (1947). Complete preemption will likewise be inferred where the field is one in which the federal interest is so dominant that the federal system will preclude enforcement of state laws on the same subject. *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982). Finally, even where Congress has not completely displaced state regulation in a specific area, state law is preempted to the extent that it actually conflicts with federal law, either because it proves impossible to comply with federal and state law simultaneously (*Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142-143 (1963)) or because state law stands as an impediment "to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). See also, *e.g.*, *Capital Cities Cable, Inc.* v. *Crisp*, No. 82-1795 (June 18, 1984), slip op. 5-6. These principles apply with equal force to federal statutes and regulations alike. *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 6; *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153-154.

As this Court has repeatedly cautioned, however, preemption will not be presumed absent a clear manifestation of congressional or agency intent to supersede state legislation. See *New York Department of Social Services* v. *Dublino*, 413 U.S. 405, 413-414 (1973) (collecting cases). As the Court noted in *Dublino* (413 U.S. at 415), "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." Accord, *de Canas* v. *Bica*, 424 U.S. 351, 359 (1976). For that reason, the Court has frequently rejected preemption attacks on laws enacted pursuant to a state's police powers that paral-

leled federal law on the same subject or imposed more stringent requirements.[10] Moreover, by centralizing legislative authority in a manner inconsistent with "the presuppositions of our embracing federal system" (*de Canas* v. *Bica*, 424 U.S. at 360-361 (citation omitted)), complete preemption disables the states and localities from tailoring legislation to address local needs. Accordingly, "[p]reemption of state law by federal statute or regulation is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained.'" *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981), quoting *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142; see also *Alessi* v. *Raybestos-Manhattan, Inc.*, 451 U.S. 504, 522-523 (1981) (collecting cases).

[10] See, *e.g.*, *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190 (1983) (state statute conditioning construction of nuclear power plants on findings of economic viability by state agency not superseded by federal regulation of nuclear power plants); *Florida Lime & Avocado Growers, Inc.* v. *Paul*, *supra* (state statute prohibiting importation of avocados with oil content below a certain value not preempted by Department of Agriculture marketing order allowing interstate shipment of avocados whose maturity was measured by a different standard); *Huron Portland Cement Co.* v. *City of Detroit*, 362 U.S. 440 (1960) (city smoke abatement code sustained against claim that federal inspection laws for maritime vessels preempted such local regulation); *California* v. *Zook*, 336 U.S. 725 (1949) (state law prohibiting same conduct by motor carriers that was prohibited by federal law not preempted); *Maurer* v. *Hamilton*, 309 U.S. 598 (1940) (state statute prohibiting operation on state highways of "above the cab" carrier vehicles not preempted by Interstate Commerce Commission's licensing of such vehicles to operate interstate).

2. As the court of appeals observed (J.S. App. A11), Section 15 of Ordinance 80-12 incorporates by reference the FDA regulations governing blood plasma and plasmapheresis at 21 C.F.R. Part 640, Subpart G, as well as any future amendments to those regulations (J.S. App. A39). The Hillsborough County regulatory scheme also imposes additional licensing, donor certification, donor examination, recordkeeping, reporting, and inspection requirements, as well as fees (*id.* at A33-A42), and makes it a crime, subject to fines or imprisonment, to violate Ordinance 80-12 (J.S. App. A38). The court of appeals found that six of these additional requirements were objectionable (*id.* at A11 n.6): (1) a person may not donate plasma until he has obtained a donor registration card, at a cost of $2, which is valid for six months at a single designated plasma center; (2) before obtaining a donor registration card, a donor must receive a complete physical examination, including a test for hepatitis; he must receive a "Certificate of Good Health," as required by FDA regulations (see 21 C.F.R. 640.63(b)(3)); and he must present a sworn statement that he has not been treated for chronic or acute alcoholism during the past year;[11] (3) prior to plasmapheresis, each donor must undergo a breath analysis for alcohol content;[12] (4) each plasma center must retain and daily forward to the county health department records of each donor and plasmapheresis pro-

[11] A potential donor must also produce one of the six types of identification specified at Section 2.A of the County's regulations (see J.A. App. A40).

[12] Section 4 of the County's regulations provides that the analysis must be performed on a designated type of equipment or one of equal quality (see J.S. App. A41).

cedure performed at the center;[13] (5) the county health department is empowered to conduct at least annual inspections, without providing notice beforehand, of each plasmapheresis center; and (6) each center is taxed no more than $1 for each plasmapheresis procedure it performs in order to offset the administrative costs of the County's regulatory system.

The court of appeals ruled that these additional requirements were implicitly but completely preempted by the FDA's regulations. With one possible exception, we disagree with the court of appeals' conclusion.

B. The Public Health Service Act And The Federal Food, Drug, And Cosmetic Act Do Not Completely Preempt The County's Regulatory Scheme

The court of appeals correctly ruled (J.S. App. A7) that Ordinances 80-11 and 80-12 and their implementing Rules and Regulations are not expressly or impliedly preempted by any federal statute. Whole blood and its components, such as blood plasma, are subject to regulation by two federal statutes. The Public Health Service Act establishes licensing, labeling, and product standards for blood, blood components, including blood plasma, and blood products (42 U.S.C. 262), and the Federal Food, Drug, and Cosmetic Act, among other things, forbids the shipment in interstate or foreign commerce of adulterated or misbranded drugs (21 U.S.C. 331(a) and (b)), which includes blood components such as blood plasma. See page 2 & notes 1 & 2, *supra*.

While both statutes authorize the Secretary to regulate the interstate manufacture and sale of blood plasma, neither Act expressly forbids the states or

[13] Section 6(A) of Ordinance 80-12 also specifies certain types of information that must be included in these records (see J.S. App. A34).

local governments from adopting supplementary regulations governing the collection of blood or its components or plasmapheresis. Moreover, notwithstanding the fact that both Acts should be liberally construed in order to protect the public health (see *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *United States* v. *Dotterweich*, 320 U.S. 277, 284 (1943)), neither statute can reasonably be interpreted to imply the congressional intent to foreclose all supplementary state and local regulation of this narrow subject.

The legislative history of the Public Health Service Act[14] and the Federal Food, Drug, and Cosmetic

[14] The current version of 42 U.S.C. 262 traces its lineage to the Act of July 1, 1902, 42 U.S.C. (1940 ed.) 141-148, which was enacted to regulate the interstate sale and transportation of viruses, toxins, and analogous products. S. Rep. 1980, 57th Cong., 1st Sess. (1902); H.R. Rep. 2713, 57th Cong., 1st Sess. (1902); 35 Cong. Rec. 7644, 7754 (1902). Congress readopted that Act in 1944 as part of a general recodification and revision of the public health laws. The Public Health Service Act of 1944, ch. 373, § 351, 58 Stat. 702. The Public Health Service Act was thereafter amended in minor respects, not relevant here, in 1958. Act of Sept. 2, 1958, Pub. L. No. 85-881, § 2, 72 Stat. 1704. The provision in 42 U.S.C. 262 governing "blood, blood component[s] or derivative[s]" was added to Section 351 of the Public Health Service Act by Section 291 of the Heart Disease, Cancer, Stroke and Kidney Disease Amendment of 1970, Pub. L. No. 91-515, 84 Stat. 1308. Congress adopted that amendment in order to overrule the Fifth Circuit's decision in *Blank* v. *United States*, 400 F.2d at 303-305, which had held that blood components used in blood transfusions, such as blood plasma, were not biological products within the meaning of Section 351 of the Public Health Service Act. See 116 Cong. Rec. 31017 (1970) (remarks of Sen. Dominick); *ibid.* (remarks of Sen. Yarborough).

At no time throughout the history of 42 U.S.C. 262 has Congress ever suggested that supplementary state or local

Act [15] also discloses no congressional intent wholly to

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regulation of blood, blood components or products, or plasmapheresis is completely preempted by federal law.

[15] The forerunner of the current Act was the Federal Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 *et seq.* That Act, like the current version, forbade, inter alia, the sale or shipment in interstate commerce of adulterated or misbranded food or drugs. See H.R. Rep. 2118, 59th Cong., 1st Sess. 3 (1906); *United States* v. *Generix Drug Corp.*, 460 U.S. 453, 457-458 (1983); *Savage* v. *Jones*, 225 U.S. 501, 529 (1912). While the Act was designed in part to fix uniform standards for food and drugs that are shipped in interstate or foreign commerce (see, *e.g.*, H.R. Rep. 2118, *supra*, at 4-5; 40 Cong. Rec. 1417 (1906) (remarks of Sen. Heyburn)), Congress did not intend to regulate wholly-intrastate activities, but left the regulation of such local matters to the states (*ibid.*; *id.* at 2652 (Sen. Money); *id.* at 2758 (Sen. Heyburn)). Plasmapheresis, which was not mentioned during the debates on the Act (see page 17 note 16, *infra*) and which is performed on a local basis, would thus not have been preempted by that Act. Cf., *e.g.*, *Corn Products Ref. Co.* v. *Eddy*, 249 U.S. 427, 433-440 (1919) (Food and Drug Act does not preempt state law fixing labeling requirements); *Savage* v. *Jones*, 225 U.S. at 529-539 (same). Compare *McDermott* v. *Wisconsin*, 228 U.S. 115 (1913) (Food and Drug Act preempts state law making state labeling requirements exclusive).

In 1938, Congress replaced the 1906 Act with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* Congress amended the Act in pertinent part in the Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87-781, 76 Stat. 780 *et seq.* While the 1906 Act only forbade the introduction of adulterated or misbranded drugs into interstate commerce, the current version of the Act, as relevant here, establishes a premarketing clearance system, under which a "new drug" cannot generally be introduced into interstate commerce until the Secretary finds that it is both safe and effective for its intended use. See *United States* v. *Generix Drug Corp.*, 460 U.S. at 458; *United States* v. *Rutherford*, 442 U.S. 544, 546-548 (1979); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-613 (1973). Neither that modification of the 1906 Act nor the legislative history of the

bar the states or localities from legislating in the plasmapheresis field.[16] Furthermore, the FDA does not construe these Acts to have that effect, and the agency's construction of the statutes it is entrusted to administer is entitled to substantial deference from the courts. See *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, No. 82-1005 (June 25, 1984), slip op. 6-7 & n.14 (collecting cases). Finally, the Hillsborough ordinances and regulations do not compel TPC to take any actions that are inconsistent with the requirements of either federal statute (see *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142-143), and the narrow compass of the County's measures does not interfere with the purposes of these federal Acts (see *Hines* v. *Davidowitz*, 312 U.S. at 67). Accordingly, unless the FDA's regulations governing blood and blood products provide a basis for preemption, the judgement of the court of appeals must be reversed.

1938 Act or the 1962 amendments discloses any congressional intent to preempt state or local regulation of plasmapheresis or to direct the FDA to do so. In fact, Section 202 of the 1962 amendments, 21 U.S.C. 321 note, provides that the amendments do not preempt state law absent "a direct and positive conflict" with the amendments (H.R. Conf. Rep. 2526, 87th Cong., 2d Sess. 15, 26 (1962); 108 Cong. Rec. 22040 (1962) (remarks of Sen. Kefauver)). See also *Pharmaceutical Soc'y* v. *Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (state law permitting pharmacists to substitute generic for prescription drugs with attending physician's approval not preempted by Federal Food, Drug, and Cosmetic Act).

[16] That conclusion is hardly surprising. Plasmapheresis not only is performed on a local basis, but also did not become a common means of collecting blood until suitable plasma collection containers were developed during the early 1960's (see 37 Fed. Reg. 17419-17420 (1972); 2 Tr. 179).

C. The FDA's Plasmapheresis Regulations Do Not Completely Preempt The County's Regulatory Scheme

1. Two points merit discussion at the outset. First, as explained above, Congress did not itself decide whether supplementary state and local regulations should be forbidden; rather, Congress left that decision to the agency's discretion. The sole question before the Court, then, is not whether Congress intended to preempt state authority in this field, but whether the FDA intended to do so (*Capital Cities Cable, Inc.* v. *Crisp*, slip op. 6-7; *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153-154). On that question, the FDA's construction of its own regulations is entitled to substantial deference from the courts (*Udall* v. *Tallman*, 380 U.S. 1, 16-17 (1965); *Bowles* v. *Seminole Rock & Sand Co.*, 325 U.S. 410, 413-414 (1945)). Where the construction of an agency's own regulations, rather than a statute, is at issue, " 'the ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation.' " *Udall* v. *Tallman*, 380 U.S. at 16-17, quoting *Bowles* v. *Seminole Rock & Sand Co.*, 325 U.S. at 413-414; accord, *United States* v. *Larionoff*, 431 U.S. 864, 872 (1977).

Here, that construction is dispositive. The FDA's blood plasma regulations, as the court of appeals acknowledged (J.S. App. A7), do not in terms preempt state or local regulation of this field. Nor can those regulations be reasonably construed to imply that intention. Indeed, the FDA made this precise point at the time it promulgated the plasmapheresis regulations.[17] In response to comments expressing

[17] These regulations, currently found at 21 C.F.R. Part 640, were originally issued in 1973 as 21 C.F.R. Part 273 and were later transferred to their current position as part of a general reorganization and recodification of the FDA's regulation of biological products (see 38 Fed. Reg. 32048 (1973)).

concern that the regulations governing the licensing of plasmapheresis facilities "would pre-empt State and local laws governing plasmapheresis" (38 Fed. Reg. 19365 (1973)), the FDA explained that (*ibid.*):

> [t]hese regulations are not intended to usurp the powers of State or local authorities to regulate plasmapheresis procedures in their localities. Rather, the intention is to assure the safety, purity, and potency of this biological product when it is shipped in interstate commerce pursuant to section 351 of the Public Health Service Act.

The FDA thus made clear that its regulations were not originally intended wholly to displace the states or municipalities from this field. While the FDA has often modified the plasmapheresis regulations since they were issued in 1973 (see, *e.g.*, 47 Fed. Reg. 30968 (1982)), the agency has not departed from its initial statement that these regulations were not intended to preempt state or local plasmapheresis regulations. Accordingly, there is no reason to construe those regulations in that fashion today.

Second, the Court ruled in *Fidelity Federal* that, when a federal agency adopts regulations that are intended to preempt state law, a reviewing court's inquiry includes the determination whether the agency's decision " 'represents a reasonable accommodation of conflicting policies' " and "is within the scope of the [agency's] delegated authority." 458 U.S. at 154, quoting *United States* v. *Shimer*, 367 U.S. 374, 383 (1961); accord, *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 6. That inquiry is wholly unnecessary, however, when the agency has disclaimed any intent to preempt state law. There is no rule of administrative

law requiring a federal agency, in the absence of an express congressional directive, to preempt local authority over a particular field, and, for the reasons given above, there can be no claim that Congress has directed the FDA to preempt the exercise of local authority in the field of blood plasma (see pages 14-17, *supra*). There is also certainly no presumption in favor of complete preemption; in fact, the presumption runs the other way (see *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 206 (1983); *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. at 230). Hence, once a reviewing court concludes that the agency did not intend to oust the states from a particular field, no further review is necessary. For that reason, while the FDA is clearly empowered to preempt local regulations like those at issue in this case, the FDA's decision not to do so at this time cannot be challenged.

Therefore, because the FDA's statement of its intent provides a sufficient basis by itself for resolving the issue in this case, the court of appeals erred even by considering whether the FDA had impliedly preempted the County's ordinances and regulations. In any event, the reasons given by the court of appeals for concluding that the FDA had impliedly preempted the County's regulatory scheme are unsound, as we will now demonstrate.

2. The court of appeals concluded that the County's ordinances were implicitly preempted because of three factors: (a) the "comprehensive" nature of the federal regulations (J.S. App. A8-A9), (b) the "dominan[ce]" of the federal interest in the field of blood plasma regulation (*id.* at A9-A10), and (c) the court's perception that enforcement of state law would present a "serious danger of conflict" with the administration of the federal regulations (*id.* at A10-A11). Except with respect to one provision of the

ordinances and regulations, we disagree with the court of appeals' conclusion.

a. As the court of appeals itself noted (J.S. App. A9), the fact that the FDA's blood plasmapheresis regulations are broad in scope and cover most aspects of the plasmapheresis process does not alone establish that the agency intended completely to displace state or local regulatory efforts in the same area. The FDA is entrusted with the responsibility of ensuring that an adequate supply of safe, pure, and potent blood, blood components, and blood products exists to meet the nation's medical and scientific needs. In discharging that obligation, the FDA has also acted to ensure that the process for collecting and manufacturing such items does not endanger the health of donors both for their own sake and for the purpose of maintaining a healthy donor population. See, *e.g.*, 37 Fed. Reg. 17420 (1972); 38 Fed. Reg. 2965 (1973); *id.* at 19362; 39 Fed. Reg. 26161 (1974); 41 Fed. Reg. 10762-10763 (1976). The obvious complexity and technical nature of the subject matter necessarily required the FDA to adopt a comprehensive regulatory approach for this field in order to accomplish its dual goals. A detailed regulatory scheme thus "was both likely and appropriate, completely apart from any questions of preemptive intent." *Dublino*, 413 U.S. at 415; see also *de Canas* v. *Bica*, 424 U.S. at 359-360. Accordingly, while the detailed nature of a federal regulatory scheme may often provide a strong reason for inferring preemption, in this case that inference would be negated by the combination of other relevant considerations.

b. The court of appeals erred in finding that the federal interest in the area of blood plasmapheresis is so dominant as to preclude state or local laws that serve valid local interests and do not interfere with the FDA's regulatory scheme. Certainly, this field is

not one, like foreign relations, in which the national interest is so ascendant that it will necessarily displace state laws that either "complement" federal law or impose "additional or auxiliary regulations" (*Hines* v. *Davidowitz*, 312 U.S. at 66-67; see also *Zschernig* v. *Miller*, 389 U.S. 429, 440-441 (1968)) regardless of Congress's stated intent. Moreover, there is no reason at present to believe that the field of blood plasma regulation is intrinsically a subject in which national policies will inevitably be disrupted if the states and local governments also share in the effort to protect the public health.

Nor is there an express statement of congressional or agency policy that the federal interest in this field is so dominant that any additional regulations will necessarily disrupt federal goals or interests. The National Blood Policy referred to by the court of appeals (J.S. App. A9) was established in 1974 by the Department of Health, Education, and Welfare (HEW) as "a pluralistic and evolutionary approach to the solution of blood collection and distribution problems" (39 Fed. Reg. 32702 (1974)). Rather than establish a federal monopoly over this subject, the National Blood Policy was designed to stress cooperative efforts among the federal government and the public and private sectors (*id.* at 32702, 32703). Although FDA statements at the time this policy was announced recognized the significant role federal regulation was likely to play in its implementation, the policy, as originally announced, expressly stated that it was not intended to encompass the plasmapheresis area, which was to be addressed at a later date (*id.* at 32702). Nothing in this policy statement suggested that HEW or the FDA had any intention to regulate blood banking activities to the exclusion of state or local governments. The National Blood Policy, by itself, thus provides no basis for inferring complete preemption.

In ruling that the federal interest in plasmapheresis is dominant over any local interest, the court of appeals relied (J.S. App. A9-A10) upon the FDA's statement that the National Blood Policy was adopted to "assur[e] uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation." 39 Fed. Reg. 18614 (1974); see also *id.* at 32703. The court of appeals may thus have found that the FDA's narrower interest in uniformity was dominant. If so, that conclusion interprets the federal policy too broadly. Cf. *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. at 205-212.

The federal government has required vendors nationwide to be subject to the same minimum product and donor safety standards to further the two-fold interest in ensuring that the national supply of safe, pure, and potent blood plasma remains adequate to meet the nation's health care needs and in protecting the health of donors for their own sake and to provide a healthy donor population. To that extent, the federal interest in plasmapheresis is dominant and the states are foreclosed from promoting a contrary policy. But neither the National Blood Policy nor the FDA's plasmapheresis regulations expresses a dominant interest in uniformity per se at the expense of supplementary state or local regulations, like those adopted by Hillsborough County, that serve legitimate public health needs and that do not adversely affect either federal interest.

The Hillsborough regulations (with one possible exception, discussed below) fall within the range of measures that the FDA has left to the states and local governments. It goes without saying that regulations protecting the public health are a legitimate exercise of the states' police power (see, *e.g.*, *Head* v.

New Mexico Bd. of Examiners in Optometry, 374 U.S. 424, 428 (1963) (statutes addressed to the protection of the public health fall "within the most traditional concept of what is compendiously known as the police power"); *Huron Portland Cement Co.* v. *City of Detroit*, 362 U.S. at 442) and that the states have the authority to regulate the various aspects of the medical profession (see, *e.g.*, *Friedman* v. *Rogers*, 440 U.S. 1, 15 (1979); *Minnesota* v. *Martinson*, 256 U.S. 41 (1921); *Dent* v. *West Virginia*, 129 U.S. 114, 121-123 (1889)). The County's concern with the health of its citizens, as expressed in Ordinance 80-12 (J.S. App. A32-A33), is thus entirely legitimate as a general matter.[18] Moreover, the measures adopted by the County to avoid these harms—the vendor licensing provisions, the donor registration process, the physical examination, breathalyzer, and affidavit requirements, and the vendors' recordkeeping and reporting obligations—not only seek to address these concerns in a rational manner, but also do not presently threaten to impede the FDA from attaining current federal goals. The incidental loss of uniformity in the standards applied to blood plasma vendors and donors nationwide, in our view, is thus unobjection-

[18] The record in this case demonstrates that the County had a rational basis for legislating in this field. As the district court found (J.S. App. A16-A17), paying plasma donors, which TPC does (*id.* at A14; 1 Tr. 34, 57), poses the risk, not present for voluntary whole blood donors, that they will donate too frequently and thereby endanger their health. Paid plasma donors, the district court also found (J.S. App. A17), have a much higher rate of hepatitis than voluntary whole blood donors. See also 39 Fed. Reg. 32703 (1974) ("voluntary donors * * * have a lower probability of "transmitting hepatitis" than commercial donors); *id.* at 32709 ("commercial donors present a relatively high risk of transmitting hepatitis", quoting HEW Task Force, *Statement of Major Findings on Blood Banking* (July 1973)).

able. See *de Canas* v. *Bica*, 424 U.S. at 360-361 (citation omitted) (preemption disfavored "'where the activity regulated [by the State] was a merely peripheral concern of the [federal regulation]'").

To be sure, blood products are widely distributed in interstate and foreign commerce. The court of appeals thus may have been correct that ensuring a safe, pure, and adequate supply of blood plasma is predominantly a federal, rather than a state or local, concern. However, state and local governments have a strong traditional interest in protecting the health of their citizens, and regulations protecting the health of blood donors and establishing safety requirements for vendors within their jurisdictions are a legitimate exercise of this authority.[19] States and localities have

[19] In the courts below, appellee claimed (see J.S. App. A16; Appellant's C.A. Br. 13-17; 1 Tr. 6; 2 Tr. 234, 247-250) that the Hillsborough County Commissioners adopted these Ordinances in response to complaints from local merchants about the presence of public inebrients and vagrants in the vicinity of TPC and that, through these Ordinances, the County intended to eliminate plasmapheresis centers by imposing severe financial burdens on their operation. That contention is unavailing, however. The Court has often noted that the quest to discover a legislature's motives for enacting a law is usually a fruitless endeavor because "[w]hat motivates one legislator to vote for a statute is not necessarily what motivates scores of others to enact it" (*Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. at 216; see also *Michael M.* v. *Superior Court*, 450 U.S. 464, 469-470 (1981) (plurality opinion); *United States* v. *O'Brien*, 391 U.S. 367, 383-384 (1968)). What is more, that inquiry is "particularly pointless" under the Supremacy Clause (*Pacific Gas & Electric Co.*, 461 U.S. at 216). Just as a local legislature may not frustrate federal law simply by adopting an ordinance with some other purpose in mind (*Perez* v. *Campbell*, 402 U.S. 637, 651-652 (1971)), so too an ordinance that does not otherwise conflict with federal statutes or policies is not preempted even if the local legislature intended to be obstructive (*Pacific*

also historically shared with the federal government an interest and an active role in assuring a safe and adequate supply of blood. For example, many federally licensed blood banks are concurrently licensed by states in which they are located. See 39 Fed. Reg. 32710, Table 1 (1974); 37 Fed. Reg. 17419 (1972). Accordingly, we are not prepared to say that at this time the federal government's interest in regulating blood and plasma products is so dominant that it precludes enforcement of state laws that are consistent with the federal regulatory scheme.

c. It follows that Hillsborough's ordinances and regulations are not preempted unless it is impossible to comply with them without violating the FDA's regulations or without frustrating the objectives of the federal regulatory program. Here, compliance with both federal and state regulations is not "a physical impossibility." *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142-143. Indeed, the Hillsborough ordinances expressly incorporate the FDA's plasmapheresis regulations, and, with one possible exception, nothing in the ordinances or implementing regulations requires actions that would violate the federal rules. For instance, the federal regulations do not forbid local governments from adopting a donor identification card requirement, like the one at Sections 4 and 5 of Ordinance 80-12, which is

Gas & Electric Co., 461 U.S. at 216). In either case, what counts is the effect of the ordinance upon federal laws or policies, not the legislators' motives for adopting the ordinance.

It also deserves mention that the County has a legitimate interest in preventing alcoholics from jeopardizing their health by excessively selling their blood plasma or by submitting to plasmapheresis without appreciating the consequences of doing so. In fact, the district court found that the health risks resulting from excessive donations of blood plasma (J.S. App. A16) are particularly acute for chronic alcoholics suffering from liver malfunction (*ibid.*).

designed to ensure that persons do not donate plasma at more than one plasmapheresis center within the time period set by the FDA. The FDA's regulations require each plasmapheresis center to obtain the donor's informed consent prior to undergoing plasmapheresis (21 C.F.R. 640.61), but those rules do not forbid a local government from requiring a potential donor to pass a breath analysis for alcohol content as part of obtaining his informed consent, as Section 7 of Ordinance 80-12 requires. The Hillsborough regulatory scheme also provides for local inspections of plasmapheresis facilities, but does not impose any health or safety requirements that are inconsistent with federal law.[20] And the FDA's regulations also offer no immunity from the fees imposed by the County upon commercial blood plasma donors and vendors.

With one possible exception, it also does not appear at this time that the Hillsborough ordinances and regulations "stand[] as an obstacle to the accomplishment * * * of the full purposes and objectives of [the FDA]." *Hines* v. *Davidowitz*, 312 U.S. at 67. The Hillsborough provisions requiring local licensing, certification of donors, recordkeeping, reporting, and inspection are more stringent than, but are not inconsistent with, the federal regulations. The court of appeals found (J.S. App. A11) that these provisions are "burdensome and expensive" and that they threaten "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors." Overly restrictive local legislation

[20] Appellee claims (Mot. to Aff. 14) that the inspection provisions of the County's scheme threaten to subject TPC to local requirements that are inconsistent with those imposed by the FDA. That risk is speculative at present, however, because the current version of the County's ordinances and regulations do not themselves have that effect.

could threaten the national plasma supply, and the cumulative effect of widespread adoption of regulations like those at issue here could, by raising the cost to firms like TPC of supplying blood plasma for interstate or foreign commerce, also lead to that result. But at this time the FDA has not identified such a threat.[21] Should a threat someday become apparent, the FDA possesses the authority to issue regulations preempting such local legislation. However, the FDA does not presently foresee that local ordinances like Hillsborough's will have the effect that the court of appeals envisioned.

As previously noted, the primary objectives of the FDA's plasmapheresis regulations are to ensure that plasma can be collected in such a way as to assure the safety, purity, and potency of the final products to be manufactured from it, as well as to protect plasmapheresis donors. See 39 Fed. Reg. 26161 (1974). The agency believes that its standards, if complied with, are fully adequate to achieve both goals. Nonetheless, with the limited exception noted below, the Hillsborough ordinances in question are not inconsistent with the dual federal goals of assuring product and donor safety and maintaining an adequate national supply of blood. Under these circumstances, the court of appeals erred by finding complete preemption in this case.

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[21] Nor is there any basis in this record for the court of appeals' conclusion. With the exception of the breathalyzer requirement, the district court found (J.S. App. A15, A18) that appellee's claims of burden and added expense in complying with the ordinances were speculative and that there was no factual basis in the record for appellee's claim that the donor population would decrease significantly if the ordinances were enforced. The court of appeals did not rule that these findings were clearly erroneous (see *Pullman-Standard* v. *Swint*, 456 U.S. 273 (1982)); nor did the court identify any basis for such a ruling.

II. THE FDA'S REGULATIONS MAY PARTIALLY PREEMPT THE COUNTY PROVISIONS THAT FORBID CERTAIN DONORS FROM UNDERGOING PLASMAPHERESIS UNLESS THEY HAVE FIRST OBTAINED A CERTIFICATE OF GOOD HEALTH

In one respect, the County's ordinances and regulations may conflict with federal regulations. By virtue of Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations (J.S. App. A35, A40), plasma donors are in every case prohibited from receiving a donor registration card necessary to undergo plasmapheresis until an examining physician issues a "Certificate of Good Health as required by [21 C.F.R. 640.63(b)(3)]." Under 21 C.F.R. 640.75, however, the FDA may authorize specific plasmapheresis facilities to collect blood from donors who have tested positive for hepatitis B surface antigen or have other conditions that render them, by any reasonable medical description, not in "good health," as required by 21 C.F.R. 640.63(c).

If the Hillsborough measures apply to plasmapheresis centers that hold such an exemption from the FDA, those measures would expressly conflict with the FDA's regulations in this respect and would thus be invalid. See *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 12-16. Moreover, the Hillsborough provisions would also directly prevent private plasmapheresis centers from carrying out a valuable federal policy in this respect. The collection of plasma from individuals with hepatitis, under carefully controlled conditions, is necessary to produce the vaccine used to prevent hepatitis (21 C.F.R. 610.41), as well as the diagnostic products used to identify the presence of disease. The Hillsborough provisions, by interfering with the ability of private plasma vendors and donors to contribute towards the amelioration of disease, would "stand[] as an obstacle to the accomplishment

and execution of the full purposes and objectives of the [FDA]" (*Hines* v. *Davidowitz*, 312 U.S. at 67). Accordingly, Hillsborough's ordinances and regulations would be preempted to the extent that they preclude donors who are or have been hepatitis-reactive or who are otherwise not in good health from donating plasma in a manner consistent with specific exemptions granted by the FDA under 21 C.F.R. 640.75. See also *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 7-16.

There are two reasons, however, why it may be unnecessary for the Court to decide that question in this case. First, appellee appears to lack standing to raise this specific claim. To our knowledge, the complaint does not allege that either appellee AML or TPC currently holds an exemption under 21 C.F.R. 640.75. Thus, appellee cannot contend that the Hillsborough ordinances and regulations prevent it from engaging in conduct expressly authorized by federal law. Second, while the matter is not entirely clear,[22] the County's provisions may incorporate the exemptions granted to specific plasmapheresis centers by the FDA. If so, preemption would be inappropriate.

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[22] Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations in terms forbid a person from undergoing plasmapheresis until he has received the certificate that these provisions require. However, the state courts may be able to reconcile these portions of the County's regulatory scheme with the FDA's regulations (see, *e.g.*, *de Canas* v. *Bica*, 424 U.S. at 357 n.5). Otherwise, if the County intended to incorporate all of the FDA's regulations, including the exemption provisions, the County can easily issue a new regulation making clear that the FDA's exemption process is also incorporated into the local regulatory scheme.

CONCLUSION

With the reservations stated in Point II of this brief, the judgment of the court of appeals should be reversed and the case remanded to that court for further proceedings to resolve the issues that were not addressed by the court of appeals.

Respectfully submitted.

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